UNECE WP on Regulatory Cooperation and Standardisation Policies

Market Surveillance glossary update

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1. Introduction

- ✓Title: Common definitions and terminology in Market Surveillance
- ✓Current version dates of 2011
- ✓Scope: Market surveillance of non-food products

1. Introduction

✓New terms and changes of terms of the 2011 edition discussed during the Moscow meeting of July 2019

✓Edited 2011 glossary document sent to members of a small working group in Nov. 2019

✓No inputs on the draft glossary doc received until now (but high interest of OIML in this document was noted)

✓Better approach for identifying serious risk products by identifying spread of uncertainty of sub-injury scenarios is needed. This would imply adding relevant statistical terms.

2. Why to review the document?

- ✓Challenge of internet sales and new actors on the market to put products on the market.
- ✓Increased market surveillance actions worldwide to counter existence of non-conform (counterfeited) products on the market.
- ✓More advanced concepts of market surveillance needed to increase effectiveness.
- ✓To incorporate latest changes of terms/definitions coming from basic/other standards and regulatory documents. (e.g. ISO/IEC 17000 latest 2020 version)

3. Objective of the document

- ✓To provide a global, harmonized set of terms and definitions to be used as a reference when drafting regulations, standards and other documents, with respect to market surveillance of non-food products placed or made available on the market.
- ✓To be in compliance with the WTO/TBT agreement.
- ✓To consider international regulations and other guidance documents (in particular new MS regulation 2019/1020/EU published on 25/6/2019).

4. Proposed changes

Changes to the 2011 glossary edition can be broken down into 2 levels:

-New terms

-Changed terms

4. Proposed changes

New terms

- ✓Market survey
  - ✓ Assessment of administrative or technical properties of products to assess whether they comply with the applicable requirements as laid down in legislation and standards. This includes, but is not limited to, inspection of marking and instructions, examination of technical documentation and testing of products.
- ✓Conformity rate
  - ✓ The conformity rate is the share of products on the market that conform to legal requirements.

4. Proposed changes

Other new terms

- ✓Fulfillment service provider
- ✓Information society service provider
- ✓Online interface
- ✓Non-compliance
- ✓Customs authorities
- ✓Products entering the country
- ✓Release for free circulation

4. Proposed changes

Other new terms

- ✓End user
- ✓Corrective action
- ✓Voluntary measure
- ✓Products presenting a risk
- ✓Products presenting a serious risk
- ✓Statistically relevant market survey action

4. Proposed changes

Changed terms

- ✓Market Surveillance
- ✓Economic operator
- ✓Risk
- ✓Withdrawal

4. Proposed changes

Other changes

- ✓Update introduction of the document
  - ✓ Add history
  - ✓ Purpose of the document
- ✓Update list of documents used

5. Uncertainty of risk assessment results

Section 5.3.6 of ISO 31010 Risk Management – Risk Assessment Techniques:

“There are often considerable uncertainties associated with the analysis of risk. An understanding of uncertainties is necessary to interpret and communicate risk analysis results effectively.”

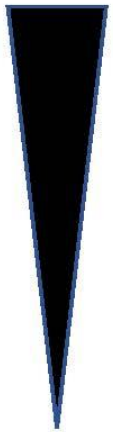
“Uncertainty analysis involves the determination of the variation or imprecision in the results, resulting from the collective variation in the parameters and assumptions used to define the results.”

“The completeness and accuracy of the risk analysis should be stated as fully as possible. Sources of uncertainty should be identified where possible…”

5. Uncertainty of risk assessment results

Risk assessment is highly sensitive to variations in the initial assumptions (different expert opinion) and can shift a product from one risk level to another.

Probability of occurrence of the harm scenario during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High	> 50 %	High risk	Serious risk	Serious risk	Serious risk
	> 1/10	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/100	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/1.000	Low risk	High risk	Serious risk	Serious risk
	> 1/10.000	Low risk	Medium risk	High risk	Serious risk
	> 1/100.000	Low risk	Low risk	Medium risk	High risk
	> 1/1.000.000	Low risk	Low risk	Low risk	Medium risk
Low	> 1/10.000.000	Low risk	Low risk	Low risk	Low risk



5. Uncertainty of risk assessment results

- Risk analysis is very sensitive with respect to
  - Probabilities within scenarios
  - Completeness and correctness of scenarios

- Easily, with slight change in the assumptions (in the experts opinion) one product can go from one to another risk level.

- The use of software (e.g. MATLAB) based on the Monte Carlo method is adequate tool for studying, analysing and verifying scenarios.

5. Uncertainty of risk assessment results

- Risk assessment procedures should be revised to provide guidelines and methodology for evaluation of the RA uncertainty.
- New template for risk assessment should be developed.
- Methodology (z-score) should be created for comparison of risk assessment results delivered by different authorities.

6. Preliminary conclusions & way forward

- ✓ Precision and uncertainty definition plays large role in assessing (serious) risk cases and therefore statistic terms need to be added to the market surveillance glossary document
- ✓ To integrate new/changed terms of latest ISO/IEC 17000, ISO 9000:2015 and 2019/1020/EU in existing UNECE glossary document
- ✓ Get comments of OIML (legal metrology), UNCTAD (Consumer protection).

Thank you